

Title 48 PUBLIC HEALTH-GENERAL

Part 1. General Administration Subpart 3. Licensing and Certification

Chapter 45. Ambulatory Surgical Center

Preface

Through contract with Department of Health and Human Services, the state has agreed to enforce certain federal regulations (Conditions of Participation) in addition to the licensure regulations listed below. The federal regulations which apply to this chapter are 42 CFR 416.1-416.75.

§ 4501. Definitions

A. *Ambulatory Surgical Center* means an establishment with an organized medical staff of physicians; with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures; with continuous physician services and registered professional nursing services whenever a patient is in the facility; and which does not provide services or other accommodations for patients to stay overnight; and which offers the following services whenever a patient is in the center:

1. drug services as needed for medical operations and procedures performed;
2. provisions for physical and emotional well-being of patients;
3. provisions of emergency services;
4. organized administrative structure; and
5. administrative, statistical, and medical records.

B. *Standards* means the rules, regulations and minimum standards duly adopted and promulgated by the Department of Health and Human Resources with the approval of the secretary.

C. *Division* means the Division of Licensing and Certification of the Department of Health and Human Resources.

D. *Department* means the Department of Health and Human Resources of the state of Louisiana.

E. *Secretary* means the secretary of the Department of Health and Human Resources of the state of Louisiana.

F. *Appeals agency* means the agency authorized to hear appeals as provided in Administrative Procedure Act.

G. *Physician* means a doctor of medicine, osteopathy, podiatry or dental surgery duly licensed by the state Louisiana.

H. *Medical staff* means those physicians, dentists, podiatrists and other medical practitioners who are

authorized to practice in the center according to these standards and the requirements of the governing authority.

I. *Governing Authority* means that individual or group of individuals who is legally responsible for the operation of the facility.

J. *Registered nurse* means a graduate or professional nurse duly licensed by the Louisiana State Board of Nurse Examiners.

K. *Licensed practical nurse*, abbreviated LPN, means a person duly licensed by the Louisiana State Board of Practical Nurse Examiners.

L. All adjectives and adverbs, such as adequate, approved, qualified, reasonable, reputable, satisfactory, sufficiently, suitable or substantial used in these standards to qualify a person, a procedure, equipment or building shall be determined by the secretary.

M. Where the word "shall" is used in these standards, the rule or regulation is mandatory

N. Where the word "should" is used, it indicates suggestion or recommendation but not requirements.

O. Where the word "may" is used in these standards, it is permissive or discretionary.

P. *Temporary permit* is a written authorization issued by the department in accordance with the law and these standards to an ambulatory surgical center which has not qualified for licensing to continue to operate for the limited period of time as specified in the permit.

Q. *New construction* shall include any of the following started after promulgation of these standards:

1. New buildings to be used as an ambulatory surgical center.
2. Additions to existing buildings to be used as an ambulatory surgical center.
3. Conversions of existing buildings or portions thereof for use as an ambulatory surgical center.
4. Alterations other than minor alterations to an existing ambulatory surgical center.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4503. General

Responsibilities for licensing procedures assigned to the secretary under Act 596 of 1976 shall be accomplished by the Division of Licensing and Certification in accord with Section 2137 of Act 596 and Section 256(B) of Act 513.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources. Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4505. Licensing Procedures

Licensing procedures, as set forth in various sections of the law, are summarized as follows:

1. Application for license shall be submitted annually by applicants on forms supplied by the department.
2. The center shall complete the application form and return it to the division at least 90 days prior to the expiration date of the current license, accompanied by a per annum license fee of \$500.
3. If a center is in compliance with the minimum standards, a license shall be issued by the department. The center shall be licensed to provide services without limitation or licensed to provide limited services.
4. If a center fails to meet the minimum standards but is correcting existing deficiencies, a temporary permit may be issued pending compliance with the minimum standards.
5. If a center fails to meet the minimum standards after any subsequent temporary permit issued to it has expired, a license may be denied or revoked.
6. If a license is denied or revoked, the applicant has the right of appeal as specified in within the law. The appeal procedure is subject to modifications according to the Administrative Procedures Act R.S. 49:951-968.
7. Ambulatory surgical centers are herein advised that standards and regulations of other groups, organization and entities with which the center may elect to align itself or enter into contract may exceed the standards contained herein or may address regulations and standards not addressed in these standards. Such alignments or contracts may be with third-party payers, professional organizations or state and federal governmental agencies. The fact that the center meets the state licensure law does in no way absolve the center of its requirement to meet the more stringent requirements of other entities, nor does membership in any other organization exempt the center from meeting the standards contained herein.
8. The ambulatory surgical center has been established and defined as a facility which occupies a unique position in the health care delivery system. Each center shall continuously evaluate its caseload and monitor its own direct patient care to assure that patients being treated are appropriate candidates for treatment at the center. Each center shall document its review of a representative sampling of admissions to assure that the facility is being properly utilized and to further assure that patients treated at the center could not have been more properly treated at a hospital or at a doctor's clinic.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR13:246 (April 1987).

§ 4507. Approval of Plans

A. All new construction, other than minor alterations, shall be done in accordance with the specific minimum requirements of the Office of State Fire Protection and the Office of Preventive and Public Health Services,

B. The applicant must furnish one complete set of plans and specifications to the following:

1. Division of Licensing and Certification
2. Office of State Fire Protection
3. Office of Preventive and Public Health Services

All three must approve the plans before construction is allowed to begin. When the plans and specifications have been fully reviewed and all inspections and investigations have been made including those of the Office of State Fire Protection and the Office of Preventive and Public Health Services the applicant will be duly notified whether or not the plans for the proposed ambulatory surgical center have been approved.

C. The division will retain one copy of the plans and specifications and study them in relation to all applicable requirements of these standards, and make investigations as it may deem necessary.

D. When the plans and specifications have been fully reviewed and all inspections and investigations have been made, including those of the Office of State Fire Protection and the Office of Preventive and Public Health Services, the department will within 30 days of receipt by it of reports from the Office of State Fire Protection and the Office of Preventive and Public Health Services notify the applicant whether or not the plans for the proposed ambulatory surgical center alteration or expansion have been approved. In case of disapproval, the department will within a like 30 days specify in writing the reasons therefor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources. Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4509. General

A. Ambulatory Surgical Center

Means an establishment with an organized medical staff of physicians; with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures; with continuous physician services and registered professional nursing services whenever a patient is in the facility; and which does not provide services or other accommodations for patients to stay

overnight; and which offers the following services whenever a patient is in the center:

1. drug services as needed for medical operations and procedures performed;
2. provisions for physical and emotional well-being of patients;
3. provisions of emergency services;
4. organized administrative structure; and
5. administrative, statistical, and medical records.

B. All applicable local and state fire, safety, sanitation and building codes shall be met.

C. A chief executive officer shall be named by the governing body to be responsible for assisting in developing and enforcing policies and procedures established by the center. Additionally, this officer shall be responsible for assuring that the operation of the center is in conformity with all federal, state and local laws and applicable to the operation of an ambulatory surgical center and to each component thereof. The chief executive officer shall be directly responsible to the governing body.

D. Signs or notices shall be prominently posted designating no smoking and no visiting areas. Smoking shall not be permitted in hazardous areas such as operating rooms, anesthetizing areas, recovery room, rooms where oxygen is in use and storage areas for anesthesia gases, oxygen or other volatile gases.

E. Disaster plans shall be developed for both internal and external occurrences. Quarterly drills shall be held in accordance with the plan. Documentation of these drills shall be recorded.

F. The treating or admitting physician shall be responsible for effecting safe and immediate transfer of patients from the center to a hospital when, in his opinion, hospital care is indicated. The center is responsible for developing written procedures for safe transfer of patients. The physician responsible for effective transfer shall be a member in good standing of the medical staff of one or more hospitals in the community. Refer to Medical Staff, Section 4535 of these standards.

G. Provisions for transfer or isolation of patients with a communicable or contagious disease shall be developed. Written procedure for isolation technique shall be in writing and practiced when applicable.

H. Combustible materials and volatile supplies shall be stored and handled in methods consistent with applicable sections of the Life Safety Code of 1985 (NFPA 101). The Life Safety Code of 1985 (NFPA 101) shall be used as the base for all fire and safety regulations. Also NFPA 99 shall be followed.

I. Underwriters Laboratories approved fire extinguishers shall be available in quantity and types consistent with requirements of the Office of State Fire Protection. Extinguishers shall be inspected at least annually by an outside agency who provides such services. Each extinguisher shall be tagged bearing a current inspection date.

J. Personnel assigned to work in the operating rooms and adjacent area shall be properly attired to minimize risks

of static electricity sparking.

K. A physician shall be on duty within the center until all patients have reacted and are stabilized.

L. There shall be a minimum of two operating rooms and one post-anesthesia recovery room within the center. Regulations shall require that the caseload not exceed the capabilities of the surgical suite including the recovery room.

M. The center shall adopt a dependable, individualized patient identification system.

N. Some provisions of these standards will cover topics which are addressed by the Office of State Fire Protection, the Office of Preventive and Public Health Services and/or regulations from other state and federal agencies. It is not intended for these standards to supercede or replace other standards, regulations or laws. When conflicts do occur, the more stringent or more extensive requirements or standards will prevail.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4511. Functions of the Office of State Fire Protection

A. All centers shall comply with the requirements of this Chapter relating to fire protection and it shall be the primary responsibility of the Office of State Fire Protection to determine if applicants are complying with these requirements. No license shall be issued or renewed without certification from the Office of State Fire Protection that such applicant is complying with the provisions of this Chapter, provided if the Office of State Fire Protection issues the applicant a conditional certificate, a temporary permit may be issued to the applicant.

B. Centers shall comply with *NFPA 101 (1985 edition)* and NFPA 99.

C. Shall also comply with the following requirements:

1. An approved automatic motor driven generator system shall be provided to supply electric current to the emergency system. This generator shall be of sufficient power and kilowattage to insure the continuance of service to the illumination of means of egress, exit and directional signs, alarms and alerting systems, generator set location, and illumination and selected receptacle service, in anesthetizing locations and patient care areas;
2. If the source of fuel for the motor generator is gasoline, diesel, kerosene or other fuels that are supplied independently of the public utilities, a secondary source of fuel will not be necessary;
3. If the fuel be natural gas or other fuel supplied by the public utilities, piped to the power unit, then a secondary source of fuel shall be provided such as gasoline, kerosene, L.P. gas, etc;
4. A sufficient amount of fuel shall be maintained on hand to insure the operation of the power plant for at least four hours;

5. If the power plant requires more than 15 gallons of secondary fuel for its operation, then the tank shall be of the approved coated type and shall be properly vented and buried beneath approximately two and one half feet of earth;
6. It shall be located as remote as possible from the building it is to serve or other improvements nearby;
7. If less than 15-gallon supply is required for eight hours operation of the plant, then this may be an above ground tank or one attached to the unit;
8. The generator shall not be located in the confines of the structure unless it is separated by fire-resistive partitions; and it shall not be located in the boiler room.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§4513. Functions of the Office of Preventive and Public Health Services

All facilities required to be licensed by the law shall comply with the requirements of this Chapter and the Office of Preventive and Public Health Services and it shall be the primary responsibility of the Office of Preventive and Public Health Services to determine if applicants are complying with these requirements. No license shall be issued or renewed without the applicant furnishing certification from the Office of Preventive and Public Health Services that such applicant is complying with these regulations; provided if the Office of Preventive and Public Health Services issues the applicant a conditional certificate, a temporary permit may be issued to the applicant.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4515. Scope of Chapter

The requirements of this Chapter are for the information of all applicants for licenses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4517. Buildings

A. General. The buildings shall reflect good housekeeping and shall be free of insects and rodents and when necessary, dust control measures should be employed. Equipment must be clean and in good repair for the safety and well-being of the patients.

B. Staff facilities. Facilities shall be provided for surgical and other personnel. Such facilities should include dressing rooms with toilet and lavatory facilities, including soap and towels.

C. Doors. All doors to the outside shall open outside, shall open outward and be provided with self-closing devices.

D. Stairways, ramps and elevators. All stairways, ramps and elevators shall be provided with nonskid floor surfaces and shall have handrails on both sides.

E. Heating systems. Heating systems shall be of such type and maintained and operated in such a manner to provide a comfortable temperature for patients and center personnel.

F. Ventilation. All rooms in general use shall be provided with adequate ventilation.

G. Lighting and wiring. Usable rooms and general areas of the center shall be lighted adequately by natural or artificial light including rooms where food is prepared and handled.

Adequate emergency lighting shall be provided for surgery and emergency rooms. Flash lights or battery operated lamps for emergency use shall be available for center personnel and kept in operational condition.

H. Toilet facilities. Adequate toilet facilities of the proper type shall be provided. Water closets shall be of the elongated bowl type with open front seats. Toilet rooms shall be adequately ventilated. Hot and cold water shall be provided in all lavatories, sinks and similar fixtures.

I. Accessibility. All centers constructed after the promulgation of this rule (March 20, 1988) shall comply with ANSI 117.1 for accessibility for the handicapped.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4519. Food Service

Wherever food service facilities are provided, all operation and related equipment shall comply with all applicable provisions of the Louisiana State Sanitary Code.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4521. Equipment and Storage

A. Storage. There shall be sufficient amount of suitable storage space throughout the center for all supplies and equipment, which shall include provisions for the safe separation of different items and location thereof away from foot traffic and overhead contamination.

B. Laundry and movement of washable goods. The center shall make provisions and be responsible for the proper

handling, cleaning, sanitizing and storage of linen and other washable goods. Dray carts shall be handled in a way as not to transmit communicable diseases from one section of the center to another and the carts shall be properly sanitized. Disposable bags shall be used as containers for the handling of bandages and other contaminated items from communicable disease areas. Linens shall be placed in a clean bag or other container and sterilized.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4523. Water Supply

All centers shall be provided with an adequate supply of safe and palatable water under pressure. Water must be obtained from a water supply approved by the Office of Public Health.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of the Secretary, LR 24:1946 (October 1998).

§ 4525. Plumbing, Sewage, Garbage and Wastes

A. Plumbing shall be installed and maintained in a manner so as not to create a health hazard, and must comply, with all applicable portions of the State Sanitary Code.

B. Drinking fountains, when provided, shall be of an approved angle jet type.

C. Approved type equipment shall be provided for cleaning and sterilizing bedpans.

D. Sewage shall be disposed of in a manner so as not to create a health hazard or nuisance.

E. Garbage shall be stored in covered containers of a capacity and type approved by the Office of Preventive and Public Health Services and such wastes shall be disposed of in a manner approved by Office of Preventive and Public Health Services.

F. Contaminated dressings, surgical and obstetrical wastes shall be handled in a sanitary manner and disposed of in an incinerator or by other approved method or methods.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4527. Radiation

All equipment providing a source of radiation shall be adequately shielded so as to protect operators, patients and

staff members at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4529. Patients' Records and Reports

A. System. Each center shall organize and maintain an approved medical record system. A medical record shall be maintained for every patient admitted and treated in the center.

B. Facilities. A room or area shall be designed within the center for medical records. The area shall be sufficiently large and adequately equipped to permit the proper processing and storing of records. Safeguards shall be established to maintain confidentiality and protection from fire water or other sources of damage. Filing systems must provide for accessibility and retrievability.

C. Ownership. The medical records are under the custody of the facility and shall be maintained for a period of six years. The records shall be kept on the center's premises and shall not be removed except under unusual circumstances (i.e., court orders, subpoenas, etc.).

D. Content of Patients' Basic Medical Record-The following minimum data shall be kept on all patients:

1. identification data
2. admission and discharge dates
3. medical and social history
4. physical examination
5. chief complaint or diagnosis
6. clinical laboratory reports
7. pathology report (when appropriate)
8. physician's orders
9. radiological report (when appropriate)
10. consultation reports (when appropriate)
11. medical and surgical treatment
12. progress notes and discharge notes and summary (The nature of services provided in an ambulatory surgical center will permit the inclusion of all these components in one summary.)
13. nurses' records of care given
14. authorizations, consents or releases
15. operative report
16. anesthesia report including post-anesthesia report
17. special procedures reports
18. autopsy findings (when appropriate)
19. copy of death certificate (when appropriate)

E. Signatures. Clinical entries shall be signed by the physicians, as appropriate; i.e., attending physician, consulting physician, anesthesiologist, pathologist, radiologist, etc. Nursing notes and observations shall be signed

by the professional nurse.

F. Nurses' notes. All pertinent observations, treatments and medications given shall be entered in the nurses' notes. All other notes relative to specific instructions from the physician shall be recorded.

G. Completion of the medical record shall be the responsibility of the admitting physician.

H. Individual admissions shall be cross-indexed according to diagnosis, surgical procedure and physician.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 132:246 (April 1997).

§ 4531. Other Records and Reports

A. The following indexes, records and registers are required:

1. patient's register
2. operating room register
3. death register
4. daily census report of admissions, discharges and deaths
5. records of reportable diseases as required by official state and/or federal agencies.

B. Other statistical information shall be maintained to expedite data gathering for specialized studies and audits.

C. Nothing in this Chapter is intended to preclude the use of automated or centralized computer systems or any other techniques provided the regulations stated herein are met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4533. Governing Authority

A. The center must have an effective governing body. The governing body is the ultimate authority of the center, and as such, it shall adopt bylaws, rules and regulations which address its responsibilities as outlined, specified or referenced in Part IV of Title 40 of the Louisiana Revised Statutes.

B. The responsibilities shall include but not be limited to:

1. organization and administration of the center.
2. Act upon recommendations from the medical staff relative to medical staff appointments.
3. Employment of a chief executive officer.
4. Maintenance of the physical plant equipped and staffed to meet the needs of the center.

C. The governing authority shall establish formal lines of communication with the medical staff through a liaison committee or other acceptable methods. This committee will address problems and programs of mutual concerns which cover such topics as patient care, cost containment and improved practices.

D. Minutes of meetings of the governing body shall be maintained to adequately reflect the discharging of its duties and responsibilities.

E. If, due to type of ownership or other reasons, it is not possible or practical to establish a governing body as such, then documents will reveal the persons who are legally responsible for the conduct of the center and are also responsible for carrying out the functions herein pertaining to the governing body.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources. Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4535. Medical Staff

A. The center shall have an organized medical staff which is responsible to the governing authority of the center for the quality of all medical care provided patients in the center and for the ethical and professional practices of its members.

B. The medical staff shall formulate and adopt bylaws, rules, regulations and policies for the proper conduct of its activities and to recommend to the governing body physicians considered eligible for membership on the medical staff. Such by-laws, rules, regulations and policies must be in writing and must be approved by the governing body.

C. The medical staff shall meet at least semi-annually. One of these meetings shall be designated as the official annual meeting wherein at least:

1. the policies and procedures shall be reviewed;
2. the past performance of the staff and its individual members shall be evaluated;
3. recommendations relative to reappointment of its membership shall be determined;
4. the election of officers for the ensuing year;
5. and the appointment of committees, if appropriate.

Records of attendance and minutes of the meetings shall be maintained.

D. All applications for membership to the medical staff shall be reviewed by the medical staff and recommendations for appropriate action made to the governing body. The governing body by-laws shall establish time frames for response to the recommendations of the medical staff.

E. It is expected that each center will attempt to secure a written transfer agreement with at least one hospital in the community. If the hospital refuses to cooperate, the center will maintain documented evidence of its attempt to acquire such an agreement. A transfer agreement shall serve as evidence of a procedure whereby patients can be transferred to a hospital should an emergency arise which would necessitate admission to a hospital. Since it might not be possible for the center to obtain a written transfer agreement, the center's compliance with the requirements

of the next paragraph will be evidence of its capability to obtain hospital care for a patient if the need arises. Even though the center may have been successful in its attempt to secure a transfer agreement, the conditions of the following paragraphs must be met.

Each member of the medical staff of the center shall also be a member in good standing of the medical staff of at least one hospital in the community and that hospital(s) must be currently licensed by the Department of Health and Human Resources. Members of the center medical staff shall be granted surgical privileges compatible with privileges granted by the hospital for that physician.

F. The medical staff shall review and analyze at its annual meeting, or more often if necessary, the clinical experience of its members through a sampling of patients' records or other valid methods.

G. Each person admitted to the center shall be under the professional care of a member of the medical staff and no person may be admitted except on the recommendation of an attending physician.

H. There shall be a physician readily available when a patient is in the center.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40-2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4537. Personnel-General

A. There shall be an adequate number of qualified personnel to properly and safely operate each department of the center.

B. All nonprofessional employees involved in direct patient care and/or services shall be under the supervision of a qualified professional employee or staff member.

C. Employees with an infectious stage communicable disease or suspected of having same or any other mental or physical condition which could be considered as detrimental to the well-being of the patient shall be relieved from duty until clearance is given by a physician.

D. All employees shall have preemployment and annual physical examinations to protect the welfare of the patients and other personnel.

E. Personnel folders shall be maintained on each employee. Contents shall include application, current license (when required), physical examination report, orientation checklist and other pertinent information as deemed necessary by the center.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4539. Nursing Personnel

- A. There shall be an organized nursing service department, including a plan of administrative authority with written delineation of responsibilities and duties for each category of nursing personnel.
- B. The nursing service department shall be under the direction of a qualified registered nurse.
- C. There shall be an adequate number of all categories of nursing personnel on duty.
- D. All registered nurses employed by the center to practice professional nursing shall have a current and valid Louisiana license.
- E. All practical nurses employed by the center to practice nursing shall have a current and valid Louisiana license.
- F. All nonprofessional employees performing nursing service functions shall be under the supervision of a registered nurse.
- G. In addition to registered nurses required to staff the surgical suite, there shall be at least one other registered nurse on duty at any time there is a patient in the center. This nurse shall be responsible for the post-surgical care of the patient and generally would be considered as being responsible for the direct nursing care provided in the recovery room. Additional registered nurses shall be employed commensurate with requirements for adequate nursing care when the patient census is a higher levels.
- H. Nursing care policies and procedures shall be in writing, formally approved and consistent with accepted nursing standards. Policies shall be developed for all nursing service procedures provided at the center. The procedures shall be periodically reviewed and revised as necessary.
- I. A formalized program of in-service training shall be developed for all categories of nursing personnel. Training shall be provided on a monthly basis and will be related to required job skills. Training provided outside the center is acceptable and encouraged.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4541. Ancillary Services Personnel

- A. If radiological and laboratory services are provided by the center, qualified personnel must be employed or contracted with to provide the services.
- B. When in-house laboratory services are provided, a qualified medical technologist, preferably registered by the American Society of Clinical Pathology, must be employed to perform tests and procedures. At the discretion of the center, with the concurrence of the medical staff other than a laboratory technologist may be authorized to perform tests and procedures. At the discretion of the center, with the concurrence of the medical staff other than a laboratory technologist may be authorized to perform the following tests: hematocrits, hemoglobin, and

urinalysis. These procedures are considered routine and this exception is granted as a cost containment measure.

C. The laboratory must provide pathologist's services, as necessary.

D. When the center provides in-house radiological services, a qualified technician shall be employed.

E. All X-rays shall be read and a written report of findings shall be made a part of the patient's record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4543. Environmental and Patient Supportive Services-General

Some supportive services and environmental aspects will be available in all centers. Other services may not be available.

In consideration of patient supportive services and environmental aspects, three approaches or situations could exist in the various centers. This Section will address the following approaches to providing services:

- a. Those services and environmental aspects which will be required of all centers and will be an in-house capability.
- b. Those services and environmental considerations which will be required but may be provided either by in-house capability or through contractual arrangements.
- c. Those services and environmental considerations which may be provided on a voluntary basis by the center and may be an in-house capability or provided through contractual arrangements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§4545. Surgery

A. There shall be a surgical area located in a segregated section of the center.

B. The surgical area shall be comprised to two or more operating rooms and must be adequate size and appropriately equipped to safely provide for the needs of the patient.

C. Each surgical suite shall be designed and equipped so that the type of surgical procedures conducted can be performed in an appropriate and acceptable manner in accordance with accepted clinical practices.

D. The surgical area shall be so located within the center as to be removed from general lines of traffic of both visitors and other center personnel.

- E. Policies and procedures shall be developed covering all services and practices applicable to the surgical department and shall be posted in the surgical suite.
- F. The following equipment will be available in the surgical suite: signaling device, cardiac monitor, resuscitator, defibrillator, aspirator, and tracheotomy set.
- G. A roster of physicians and other medical practitioners specifying the surgical privileges of each must be kept in the files of the operating room supervisor.
- H. The surgical suite must be under the supervision of a registered nurse.
- I. A qualified first assistant physician shall be present and scrubbed in any procedure where there is an unusual hazard to life. Assistants at lesser operations may be a registered nurse or surgical technician if the individuals have been designated by the center authorities as having sufficient training to properly and adequately assist in such procedures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4547. Anesthesia

- A. The surgical center must have effective policies and procedures pertaining to staff privileges of anesthesiologists, administration of anesthesia, maintenance of equipment and strict safety controls.
- B. Inhalation and area block anesthesia should be administered by a board-certified or board-eligible anesthesiologist. When this is not possible, the area block anesthesia must be administered by a doctor of medicine or a certified registered nurse anesthetist. Certified registered nurse anesthetists shall be under the supervision of an doctor of medicine.
- C. Local anesthesia, interpreted to mean those anesthetizing agents administered by needle and affecting a very small localized area may be administered by the treating physician or by qualified personnel (RN's or LPN's) under the orders and supervision of the treating physician.
- D. The patients' records shall include appropriate information relative to types and methods of administration of anesthesia.
- E. In cases involving inhalation or block anesthesia, post-anesthesia follow-up notes shall be recorded by the anesthesiologist or nurse anesthetist noting positive and/or negative findings.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4549. Recovery Room

- A. A post-surgery recovery room shall be provided of sufficient size and equipment to efficiently and safely provide for the needs of the staff and the patients. Patients shall be kept in the recovery room until adequately reacted from surgery and anesthesia.
- B. There shall be a minimum of 60 square feet per patient bed within the recovery room with complete access to both sides of the bed.
- C. Special recovery room stretchers shall be furnished to provide safety and services features.
- D. The recovery room shall be equipped with special patient services equipment such as resuscitators, aspirators, oxygen supply, and storage facilities for drugs and other supplies.
- E. Procedures shall be established and approved to cover all practices pertaining to the recovery room and shall be readily available to personnel.
- F. The recovery room should be located adjacent to the surgical suite.
- G. A registered nurse will be assigned to and directly responsible for the recovery room.
- H. Since the post-operative recovery room usually serves as the point from which patients are discharged, the nurses' station referred to elsewhere in these standards should be an integral part of the recovery room.
- I. Intercommunications systems from the patient area to the nurse's station shall not be required where there is direct visual contact between patients and staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4551. Radiology

- A. Radiological services commensurate with the needs of the center and the patients will be provided either as an in-house service or through arrangements with outside sources.
- B. Radiological determinations made by the attending physician within 72 hours prior to admission shall be acceptable if so documented by the physician and conforms with general regulations and practices of the center.
- C. All radiological determinations, except in B above, shall be in writing and the original shall be a part of the patient's chart.
- D. If in-house capabilities are provided, the area shall be of sufficient size and arrangement to provide for personnel and patient needs.
- E. The radiological equipment shall be appropriately shielded to conform with state law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources. Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4553. Laboratory

- A. The center may either provide a clinical laboratory or make contractual arrangements with an approved outside laboratory to perform services commensurate with the needs of the center.
- B. An approved outside laboratory may be defined as a free-standing independent laboratory or a hospital-based laboratory which in either case has been appropriately certified as a provider under the prevailing regulation of P.L. 89-97 Titles XVIII and XIX (Medicare-Medicaid).
- C. Such contractual arrangements shall be deemed as meeting the requirements of this Section so long as those arrangements contain written policies, procedures and individual chart. documentation to disclose that the policies of the center are met and the needs of the patients are being provided Written original reports shall be a part of the patient's chart.
- D. In-house laboratories shall be well-organized and properly supervised by qualified personnel.
- E. The laboratory will be of sufficient size and adequately equipped to perform the necessary services of the center.
- F. Provisions shall be made for a preventive maintenance and an acceptable quality control program covering all types of analyses performed by the laboratory. Documentation will be maintained.
- G. Written policies and procedures shall be developed and approved for all services provided by the laboratory.
- H. When tissue removed in surgery is examined by a pathologist, either macroscopically or microscopically, as determined by the treating physician and the pathologist, the pathology report shall be made a part of the patient's record.
- I. Arrangements shall be made for immediate pathological examinations, when appropriate.
- J. Facilities for procurement, safekeeping and transfusion of blood and blood products must be provided or readily available.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources. Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4555. Pharmacy

- A. The center shall provide pharmacy services commensurate with the needs of the center and in conformity with state and federal laws.

- B. The pharmacy or drug room shall be under the supervision of a registered pharmacist who may serve full time, part time or on a consultant basis.
- C. If there is no pharmacist on the staff, then prescription drugs are dispensed by a qualified pharmacist elsewhere and only storing and distributing are done in the center.
- D. The pharmacist will assist in writing current rules, policies and procedures for the distribution, storing and handling of drugs; monitors drug and medication-related activities in the center, and if a consultant, provides consultation on a monthly basis. Consultations must be documented showing date, amount of time, subjects, and recommendations.
- E. The center will provide facilities for proper storage, safeguarding and distribution of drugs. The following factors will be considered:
1. drugs are issued to the floor in accordance with approved policies and procedures;
 2. drug cabinets at the nursing station are constructed and organized to assure proper handling and safeguard against access to unauthorized personnel. Drug storage areas on all units are inspected by the pharmacist, at least on a monthly basis;
 3. storage areas shall have proper controls for ventilation, lighting and temperature;
 4. locked areas shall be designed to conform with state and federal laws;
 5. all floor-stored drugs are properly controlled.
- F. In accordance with all applicable laws, records shall be kept on all ordering, purchasing, dispensing, distribution of drugs and the disposal of unused drugs. Records for prescription drugs dispensed to each patient are maintained in the pharmacy or drug room containing the full name of the patient, the name of the prescribing physician, the name and strength of the drug, the quantity dispensed and the date of issue.
- G. The center, on consultation with the pharmacist and medical staff, will develop or adopt a formulary or list of drugs for use in the center. The list will be reviewed periodically and amended as appropriate by the same group or committee.
- H. Provision is made for emergency pharmaceutical service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987)

§ 4557. Sterilizing Procedures and Equipment

- A. The center shall make adequate provisions for furnishing properly sanitized, disinfected or sterilized supplies, equipment, utensils and solutions.
- B. It is expected that some disposable goods shall be utilized but when sterilizers and autoclaves are used, they shall be of the proper type and necessary capacity to adequately meet the needs of the center.

- C. Procedures for the proper use of equipment and standard procedures for processing of various materials and supplies shall be in writing and readily available to personnel responsible for sterilizing procedures.
- D. Acceptable techniques for handling sterilized and contaminated supplies and equipment shall be established to avoid contamination.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4559. Dietary

- A. These standards shall not require that dietary services be provided by the center. However, a center may elect to provide some level of service.
- B. When dietary services are provided, the standards of the Office of Preventive and Public Health Services shall prevail.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4561. Housekeeping

- A. The center shall provide housekeeping services which shall assure a safe and clean environment. The service may be provided either by house staff or through contractual arrangements with an outside agency or a combination of the two.
- B. Policies and procedures shall be in writing covering services for all areas of the center.
- C. Equipment shall be provided to adequately maintain the center and the equipment shall be maintained in a safe condition.
- D. Special attention shall be given to guard against cross-contamination and the spread of infectious organisms.
- E. All garbage and waste materials shall be collected, stored and disposed of in a manner designed to prevent the transmission of contagious diseases, and to control flies, insects, and animals.
- F. Housekeeping procedures, properly approved, shall be in writing and shall be followed.
- G. All openings to the outer air shall be maintained to protect against the entrance of insects and animals.
- H. Containers shall be washed, sanitized and/or sterilized before re turning to the work area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4563. Laundry

- A. The center shall provide for adequate laundry, either by internal capability or by contract or arrangement with an outside source.
- B. A linen inventory shall be maintained on the premises at all times to adequately meet the needs of the staff and the patients.
- C. Contaminated linens shall be collected in identifiable plastic bags and sealed prior to transport to either the laundry or the storage area for collection by the contracting laundry.
- D. If the center provides an in-house laundry, the area shall be designed in accordance with acceptable hospital laundry design in that a soiled laundry area will be provided and separated from the clean laundry area. Dirty and/or contaminated laundry shall not be stored or transported through the clean laundry area.
- E. For in-house laundry, special cleaning and decontaminating processes shall be used for contaminated linens.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4565. Patient Rooms

- A. Patient rooms, in the usually accepted sense, do not normally exist in centers and shall not be required by these standards.
- B. Standards covered under *Recovery Room and Nurses' Stations and Facilities* should be detailed enough to clearly disclose the intent of these standards.
- C. In the absence of patient rooms, the center will provide pre-surgery accommodations which assure privacy, safe storage of personal belongings and comfort for the patient while being prepared for surgery.
- D. These accommodations shall also be appropriate to the needs of patients when being discharged from the center directly from the recovery area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4567. Centers With Post-Surgery Patient Rooms

In contrast to the above standards, centers may, if they so elect, provide private or multi-bed patient rooms. The

following standards will prevail if such is the case:

1. Single patient rooms shall provide a minimum of 100 sq. ft. of floor space excluding areas for built-in closets, drawer space and other built-in features;
2. Multi-bed patient rooms shall provide a minimum of 80 sq. ft. of floor space per bed, excluding areas for built-in features as stated in (1) above;
3. No dimension in (1) or (2) above shall be less than eight feet;
4. Each room shall be furnished with a bed, chair, bedside stand, approved type waste receptacle, drawer space for each patient and a lavatory with hot and cold water for each room;
5. Each patient shall be provided with an intercommunications system interconnected with the nurses' station;
6. Each patient shall be provided with individual bedside utensils cleaned and/or sterilized as appropriate;
7. Suitable lighting shall be provided in manner so as to be controlled by the patient;
8. Beds shall be recovery type beds with special safety and services features and supplied with necessary pillows, sheets and blankets;
9. Each room shall be an outside room with a window area of clear glass of not less than one-eighth of the floor area except in rooms below grade where the window area shall not be less than one-fifth of the floor area;
10. There shall be an adequate number of bathrooms for the convenience of the patients. Each bathroom shall be equipped with an emergency call system connected with the nurses' station;
11. Privacy screens shall be available in multi-bed rooms.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1987).

§ 4569. Nursing Stations and Facilities

- A. A nurses' station shall be provided to serve the post-surgical nursing unit.
- B. The number and size of the station(s) shall be adequate to efficiently serve the needs of the staff and patients.
- C. The station shall be centrally located on the nursing unit and convenient to patients, service areas and supplies and have open vision to the nursing unit.
- D. Each station will be equipped with desk space, chart racks and telephone. Intercommunications system shall only be required when there is not direct visual contact with post-surgical patients. However, there should be an

electronic signaling system between the nurses' station and the surgical suite. Preferably, this system should have intercommunications capability.

E. When patient rooms do not exist and patients are discharged from the recovery room, the nurses' station shall be located within the recovery area and should assure direct visual contact with all patients.

F. On each nursing unit, preferably within or immediately adjacent to the nurses' station, there shall be an adequate, properly equipped area or room for the preparation, cleaning and storage of nursing supplies and equipment used on the nursing unit.

G. The nurses' station will be equipped with a cupboard, closet or room for the storage and preparation of patient drugs and medications. Separate areas shall be provided for the separation of internal and external drugs and medications. This area shall be well-lighted with adequate temperature controls and accessible only to authorized personnel. A sink with running water and sufficient work area will be provided.

H. Toilet and handwashing facilities shall be conveniently located for the convenience of the nursing staff.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2131-2143.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of the Secretary, Division of Licensing and Certification, LR 13:246 (April 1997).